

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

3-D MATRIX, INC.,
3-D MATRIX, LTD., and
MASSACHUSETTS INSTITUTE OF
TECHNOLOGY,

Plaintiffs,

v.

MENICON CO. LTD. and
B-BRIDGE INTERNATIONAL, INC.,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs 3-D Matrix, Inc., 3-D Matrix, Ltd. (collectively “3-D Matrix”) and the Massachusetts Institute of Technology (“MIT”) bring this complaint against Defendants Menicon Co. Ltd. (“Menicon”) and B-Bridge International, Inc. (“B-Bridge”) for infringement of United States Patent Nos. 5,670,483 (the “483 Patent”) and 5,955,343 (the “343 Patent”) (collectively the “Asserted Patents”).

THE PARTIES

Plaintiffs

1. 3-D Matrix, Inc. is a corporation organized and existing under the laws of Delaware and has its principal place of business at 200 West Street, Waltham MA 02451.

2. 3-D Matrix, Ltd. is a corporation having a principal place of business at 7F, Kojimachi HF Building, 3-2-4, Koji-machi, Chiyoda-ku, TKY, 102-0083, Japan.

3. MIT is a non-profit educational corporation organized and existing under the laws of the Commonwealth of Massachusetts and is located at 77 Massachusetts Avenue, Cambridge MA 02139.

Defendants

4. Menicon, upon information and belief, is a corporation organized and existing under the laws of Japan and has its principal place of business at 5-1-10 Takamoridai, Kasugai, Aichi 487-0032, Japan.

5. B-Bridge, upon information and belief, is a corporation organized and existing under the laws of the California and has its principal place of business at 20813 Stevens Creek Blvd., Cupertino, CA 95014.

NATURE OF THE ACTION

6. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271, *et seq.*

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over the Defendants in this action because Defendants have sufficient minimum contacts with the forum as a result of business conducted within the Commonwealth of Massachusetts and because Defendants have committed acts of patent infringement within the Commonwealth of Massachusetts.

9. Upon information and belief, Defendants have placed products into the stream of commerce via established distribution channels, with the knowledge, intent, and/or understanding that such products are marketed, offered for sale and/or sold within the Commonwealth of Massachusetts.

10. Upon information and belief, Menicon operates a wholly owned subsidiary within the Commonwealth of Massachusetts, Menicon America, Inc., which has its principal place of business at 281 Winter Street, Suite 180, Waltham, MA 02451.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE ASSERTED PATENTS

12. On September 23, 1997, the United States Patent and Trademark Office (“PTO”) duly and legally issued the ’483 Patent, entitled “Stable Macroscopic Membranes Formed by Self-Assembly of Amphiphilic Peptides and Uses Therefor,” to Shuguang Zhang, Curtis Lockshin, Alexander Rich and Todd Holmes. MIT is the owner by assignment of the ’483 Patent. A true and accurate copy of the ’483 Patent is attached as Exhibit A.

13. On September 21, 1999, the PTO duly and legally issued the ’343 Patent, entitled “Stable Macroscopic Membranes Formed by Self Assembly of Amphiphilic Peptides and Uses Therefor,” to Shuguang Zhang, Curtis Lockshin, Alexander Rich, Todd Holmes and C. Michael DiPersio. MIT is the owner by assignment of the ’343 Patent. A true and correct copy of the ’343 Patent is attached as Exhibit B.

14. 3-D Matrix is the exclusive licensee of the Asserted Patents in specific fields of use.

15. 3-D Matrix researches, develops, manufactures, seeks regulatory approvals for, and sells self-assembling peptide products out of its Waltham, Massachusetts location. For example, 3-D Matrix’s PuraMatrix™ product is a self-assembling peptide embodying the technology of the Asserted Patents.

16. 3-D Matrix’s PuraMatrix™ products are marked with the Asserted Patents in accordance with 35 U.S.C. § 287(a).

MENICON’S KNOWLEDGE OF THE ASSERTED PATENTS

17. The technology of the Asserted Patents was invented by a team of scientists and engineers at MIT, led by Dr. Shuguang Zhang. Dr. Zhang’s research in the area of self-

assembling peptides has spanned more than 20 years. In that time, Dr. Zhang developed self-assembling peptides having superior properties in a multitude of uses, including cell culture. Dr. Zhang has authored numerous scientific publications and delivered many lectures concerning his self-assembling peptide work, and he was recently named a Fellow of the U.S. National Academy of Inventors for 2013 for his inventive work in this field.

18. Between 2004 and 2006, Dr. Zhang accepted into his lab Mr. Yusuke Nagai, a visiting student at MIT. Dr. Zhang shared his knowledge related to self-assembling peptides, including knowledge of the technology of the Asserted Patents, with Mr. Nagai during this time.

19. On information and belief, Mr. Nagai is an employee of Menicon Co., Ltd. Mr. Nagai is identified as the first named inventor on a PCT application, filed on February 12, 2010, and first published in the United States as U.S. Patent Application Publication No. 2012/0058066 (the “’066 Publication”), entitled “Self-Assembling Peptide and Peptide Gel with High Strength.” Menicon Co., Ltd. is identified as an assignee of the ’066 Publication. A true and correct copy of the ’066 Publication is attached as Exhibit C.

20. Figures 11(a) and (b) to the ’066 Publication specifically describe the 3-D Matrix PuraMatrix™ product.

21. An information disclosure statement filed by Menicon with the PTO on September 8, 2011, cites the ’483 Patent as prior art to the ’066 Publication.

22. Mr. Nagai is the first author of a paper published in 2012 in the journal *Biomaterials*. Yusuke Nagai, *et al.*, *The mechanical stimulation of cells in 3D culture within a self-assembling peptide hydrogel*, 33 BIOMATERIALS 1044, 1049 (2012) (the “Biomaterials Paper”). Mr. Nagai is identified in that paper as being affiliated with Menicon Co., Ltd. A true and correct copy of the Biomaterials Paper is attached as exhibit D.

23. The Biomaterials Paper describes an artificial self-assembling peptide, SPG-178. The paper compares several properties of SPG-178 with a self-assembling peptide gel identified as RADA16, also identified as PuraMatrix™. The paper further states that samples of 3-D Matrix's PuraMatrix™ product were acquired by the researchers for use as described therein.

24. On information and belief, Defendants have had actual or constructive knowledge of the Asserted Patents as early as March 9, 2009, the priority date for the '066 Publication.

CLAIMS

Count I **Direct Infringement of U.S. Patent No. 5,670,483**

25. Plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, as if set forth fully herein.

26. On information and belief, Menicon makes, uses, sells, offers to sell and/or imports a product called PanaceaGel. Menicon identifies the PanaceaGel product on its website as a self-assembling peptide having the thirteen amino-acid sequence of RLDLRLALRLDLR, in which R represents arginine, a basic hydrophilic amino acid; L represents leucine, a neutral hydrophobic amino acid; D represents aspartic acid, an acidic hydrophilic amino acid; and A represents alanine, a neutral hydrophobic amino acid. A true and correct copy of a page on the Menicon website advertising the PanaceaGel product (the "PanaceaGel Product Page") is attached as Exhibit E.

27. On information and belief, B-Bridge is a licensed distributor of the PanaceaGel product in the United States. B-Bridge offers at least two forms of the PanaceaGel product for sale to customers in the United States, identified by the catalog numbers SPG-178-108 and SPG-178-104. A true and correct copy of a page on the B-Bridge website advertising SPG-178-108 for sale (the "B-Bridge Product Page") is attached as Exhibit F.

28. The amino acid sequence of the PanaceaGel product is the same amino acid sequence identified in the Biomaterials Paper as SPG-178 and the same sequence identified in the '066 Publication as SEQ ID No: 1. The PanaceaGel Product Page also contains a hyperlink entitled "Literature," which resolves to a page on the Menicon website containing a citation to the Biomaterials Paper (the "PanaceaGel Literature Page"). A true and correct copy of the PanaceaGel Literature Page is attached as Exhibit G.

29. Making, using, selling offering to sell or importing the PanaceaGel product, as described in the PanaceaGel Product Page, the Biomaterials Paper and the '066 Publication directly infringes at least one claim of the '483 Patent.

30. Defendants directly infringe and continue to infringe, literally and/or under the doctrine of equivalents, at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

31. On information and belief, Defendants' infringement of the '483 Patent will continue in the future, and Plaintiffs will continue to suffer damages as a consequence, unless Defendants' infringing acts are enjoined by this Court.

Claim II
Induced Infringement of U.S. Patent No. 5,670,483

32. Plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, as if set forth fully herein.

33. Menicon's PanaceaGel Product Page states that the PanaceaGel product will form a nanofiber-scale three-dimensional network in aqueous solvent.

34. The PanaceaGel Product Page explains that the thirteen amino acid peptide of the PanaceaGel product undergoes self-assembly in several steps to form a nanofiber structure, and recommends that the product be used as a scaffold in three-dimensional cell culture.

35. Use of the PanaceaGel product to form a nanofiber-scale three-dimensional network in aqueous solvent according to the PanaceaGel Product Page would directly infringe at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

36. Mencion's knowledge of the '483 Patent and Menicon's instructions are evidence that Menicon knows its customers' acts will constitute infringement of at least one claim of the '483 Patent, and that Menicon specifically intends its customers to infringe at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

37. On information and belief, B-Bridge has actual and/or constructive knowledge of the '483 Patent through its relationship with Menicon.

38. The B-Bridge Product Page instructs users to use the PanaceaGel product for the purpose of forming a hydrogel in an aqueous solvent. Use of the PanaceaGel product in accordance with B-Bridge's instructions would result in the creation of a product that directly infringes at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

39. B-Bridge's knowledge of the '483 Patent and B-Bridge's instructions to use the PanaceaGel product for the purpose of forming a hydrogel in aqueous solvent are evidence that B-Bridge knows its customers' acts will constitute infringement of at least one claim of the '483 Patent, and that B-Bridge specifically intends its customers to infringe at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

40. Defendants induce infringement, literally and/or under the doctrine of equivalents, of at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

41. On information and belief, Defendants' induced infringement of the '483 Patent will continue in the future, and Plaintiffs will continue to suffer damages as a consequence, unless Defendants' infringing acts are enjoined by this Court.

Count III
Contributory Infringement of U.S. Patent No. No. 5,670,483

42. Plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, as if set forth fully herein.

43. On information and belief, the PanaceaGel product is made or specially adapted solely for use in a manner that would infringe at least one claim of the '483 Patent. The PanaceaGel product is not a staple article or commodity of commerce, and has no substantial noninfringing uses. For example, the PanaceaGel product contains an amphiphilic polypeptide, SPG-178, having a 13 amino acid sequence containing alternating hydrophobic and hydrophilic amino acids which are complimentary and structurally compatible, which is specially adapted to undergo spontaneous self-assembly in aqueous solvents containing a monovalent metal cation, such as sodium.

44. On information and belief, the PanaceaGel product is only substantially useful in a manner which would infringe at least one claim of the '483 Patent. For example, on information and belief, the polypeptide of PanaceaGel has no known scientific or commercial applications unless suspended in an aqueous solvent containing a monovalent metal cation.

45. Defendants contributorily infringe, literally and/or under the doctrine of equivalents, at least claims 1-4, 9, 11-17, 21-22, 34, 37-38, 41-44 and 48 of the '483 Patent.

46. On information and belief, Defendants' contributory infringement of the '483 Patent will continue in the future, and Plaintiffs will continue to suffer damages as a consequence, unless Defendants' infringing acts are enjoined by this Court.

Count IV
Induced Infringement of U.S. Patent No. 5,955,343

47. Plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, as if set forth fully herein.

48. The PanaceaGel Product Page states that the PanaceaGel product is “for 3D Cell Culture.”

49. The PanaceaGel Product Page contains a hyperlink entitled “User Guide” which resolves to a page providing Cell Culture Protocols and a document of Frequently Asked Questions (“FAQ”). Menicon’s PanaceaGel Cell Culture Protocol for cell culture in 96 well plates is attached as Exhibit H. Menicon’s PanaceaGel FAQ is attached as Exhibit I.

50. Menicon’s PanaceaGel FAQ provides a question and answer which states:

16. Is it possible to culture cells on PanaceaGel?

Yes. PanaceaGel could be coated onto a petri-dish, insert, well or other cell culture plate before adding cell suspension. Please add cell suspension gently to avoid agitation. Protocol is under preparation.

51. Menicon’s PanaceaGel FAQ further states that the PanaceaGel Product has been used to successfully culture at least the following cell types: mouse skeletal muscle cell (C2C12); rat skeletal muscle cell (L6); mouse fibroblast (NIH3T3); human fibroblast (TIG-1); human chondrosarcoma cell (OUMS-27); and neonatal cardiac myocyte (isolated).

52. Menicon’s PanaceaGel Cell Culture Protocol provides instructions on how to begin and maintain a cell culture using PanaceaGel. The protocol involves suspending cells in a serum free cell culture medium at twice the desired cell concentration and mixing the suspension with the PanaceaGel product in a 1:1 ratio to form a PanaceaGel cell mixture. Thereafter, the protocol suggests adding a volume of the PanaceaGel cell mixture to the wells of a 96 well plate, and covering with a volume of cell culture medium. Cell culturing is begun by placing the plate in an incubator at recommended to be at 37°C and 5% CO₂. Finally, the protocol suggests replacing the cell culture medium with typical frequency.

53. Use of the PanaceaGel product for the purposes stated on the PanaceaGel Product Page, and in the PanaceaGel FAQ, and according to the instructions provided in the PanaceaGel Cell Culture Protocol, would directly infringe at least claims 1 and 2 of the '343 Patent.

54. Menicon's knowledge of the '343 Patent and Menicon's instructions in the PanaceaGel Cell Culture Protocol are evidence that Menicon knows its customers' acts will constitute infringement of at least one claim of the '343 Patent, and that Menicon specifically intends its customers to infringe at least claims 1 and 2 of the '343 Patent.

55. On information and belief, B-Bridge has actual and/or constructive knowledge of the '343 Patent through its relationship with Menicon.

56. The B-Bridge Product Page instructs users to use the PanaceaGel product for the purpose of cell culturing. Use of the PanaceaGel product in accordance with B-Bridge's instructions would directly infringe at least claims 1 and 2 of the '343 Patent.

57. B-Bridge's knowledge of the '343 Patent and B-Bridge's instructions to use the PanaceaGel product for the purpose of cell culturing are evidence that B-Bridge knows its customers' acts will constitute infringement of at least one claim of the '343 Patent, and that B-Bridge specifically intends its customers to infringe at least claims 1 and 2 of the '343 Patent.

58. Defendants induce infringement, literally and/or under the doctrine of equivalents, of at least claims 1 and 2 of the '343 Patent.

59. On information and belief, Defendants' induced infringement of the '343 Patent will continue in the future, and Plaintiffs will continue to suffer damages as a consequence, unless Defendants' infringing acts are enjoined by this Court.

Claim V
Contributory Infringement of U.S. Patent No. 5,955,343

60. Plaintiffs reallege and incorporate by reference the above paragraphs of this Complaint, as if set forth fully herein.

61. On information and belief, the PanaceaGel product is made or specially adapted solely for use in a manner that would infringe at least one claim of the '343 Patent. The PanaceaGel product is not a staple article or commodity of commerce, and has no substantial noninfringing uses.

62. On information and belief, the PanaceaGel product is only substantially useful in a manner that would infringe at least one claim of the '343 Patent. For example, on information and belief, the polypeptide component of PanaceaGel is sold exclusively for the purpose of cell culturing, and Defendants' have provided no protocols, literature examples, or methodologies for using the PanaceaGel product for any other purpose.

63. Defendants contributorily infringe, literally and/or under the doctrine of equivalents, at least claims 1 and 2 of the '343 Patent.

64. On information and belief, Defendants' contributory infringement of the '343 Patent will continue in the future, and Plaintiffs will continue to suffer damages as a consequence, unless Defendants' infringing acts are enjoined by this Court.

Willful Patent Infringement

65. Defendants' infringement of the Asserted Patents is and has been willful. Upon information and belief, despite knowledge of the Asserted Patents, despite an objectively high likelihood that their actions constituted infringement of the Asserted Patents, and despite that Defendants knew or should have known of that objective likelihood, Defendants have infringed and will continue to infringe the Asserted Patents with reckless disregard of them. Upon

information and belief, despite Defendants' knowledge of the Asserted Patents and their knowledge of their infringing acts, Defendants have taken no steps to discontinue their importation, offers for sale and sales of the PanaceaGel products or remove the PanaceaGel products from the market, and have continued their infringing acts.

PRAYER FOR RELIEF

Plaintiffs respectfully request the following relief:

- A. A declaration that Defendants have infringed the Asserted Patents under 35 U.S.C. § 271, and final judgment incorporating the same;
- B. Equitable relief under 35 U.S.C. § 283, including but not limited to, an injunction that enjoins Defendants and their officers, agents, servants, employees, representatives, successors and assigns, and all others acting in concert or participation with them, from continued infringement of the Asserted Patents;
- C. An accounting of all infringing sales and other infringing acts of Defendants;
- D. An award of damages sufficient to compensate Plaintiffs for Defendants' acts of infringement of the Asserted Patents, together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;
- E. An order finding that Defendants' infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;
- F. An order finding that this is an exceptional case under 35 U.S.C. § 285 and awarding relief, including reasonable attorneys' fees, costs, and expenses; and
- G. Such other relief as is just and proper.

JURY DEMAND

Under Rule 38 of the Rules of Civil Procedure, Plaintiffs demand a trial by jury of all issues triable to a jury.

Dated: January 27, 2014

Respectfully submitted,

By:

/s/ Craig R. Smith

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